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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,474	12/08/2003	Thomas Sandal	5600.210-US	2856
25908 7590 05/14/2008 NOVOZYMES NORTH AMERICA, INC. 500 FIFTH AVENUE SUITE 1600 NEW YORK, NY 10110				
EXAMINER JOHANNSEN, DIANA B				
ART UNIT		PAPER NUMBER		
1634				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/730,474

Applicant(s)

SANDAL ET AL.

Examiner

Diana B. Johannsen

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

FINAL ACTION

1. This action is responsive to the Amendment filed December 17, 2007 and the Terminal Disclaimer filed December 17, 2007. Claims 1, 14 and 20 have been amended. Claims 1-20 remain under consideration. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections and/or objections not reiterated in this action have been withdrawn. **This action is FINAL.**
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. As a result of applicants' amendment of independent claims 1 and 14 to recite "environmental pool comprising microorganisms" in lieu of "environmental pool of microorganisms," the examiner concurs that applicants' claims are now supported by provisional application 60/106,319, filed October 30, 1998, such that the claimed invention is now entitled to an effective filing date of October 30, 1998. Thus, the Okuta et al reference now qualifies as prior art under 35 USC 102(a), but not 35 USC 102(b). The modification of the rejection set forth below is therefore necessitated by applicants' amendments.

5. Claims 1-3, 5-6, 8-9, 12-17, and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by Okuta et al (Gene 212:221-228 [6/1998]).

Okuta et al disclose methods in which catechol 2,3-dioxygenase (C23O) gene libraries are prepared and in which DNA sequences in said libraries are identified (see entire reference, particular pages 222-224). The method of Okuta et al comprises a step of cultivating bacteria-containing samples of soil or sea water on media containing substrates for C23O genes (specifically, phenol or crude oil), followed by PCR amplification and cloning of DNA templates prepared directly from bacterial cells growing "on phenol or crude oil as the carbon source" (see pages 222-224, particularly the right column of page 223). As it is a property of the bacteria-containing soil and sea water samples that they constitute types of environmental pools comprising microorganisms, the samples employed by Okuta et al are encompassed by the instant claims. Thus, Okuta et al set forth a method meeting the requirements of independent claim 1. Regarding independent claim 14, it is further noted that Okuta et al also disclose screening the libraries prepared by their methods for DNA sequences encoding their polypeptide of interest (i.e., encoding polypeptides having C23O sequences as determined by nucleic acid sequencing; see pages 222, right column and 224, right column).

Regarding dependent claims 2-3, 15, and 20, it is again noted that the media employed by Okuta et al is disclosed by Okuta et al as being enriched with C23O substrates (specifically, phenol and crude oil), and that Okuta et al state that phenol or crude oil constitute the carbon source in their media (see above). Regarding claims 5-

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6, the phenol or crude oil containing media of Okuta et al is growth restricted in that only phenol-degrading bacteria grow on the media; further, the media pH and incubation temperature employed by Okuta et al inherently affect whatever growth occurs on said media, such that the cultivation conditions employed by Okuta et al include growth restrictions that "comprise pH and temperature," as required by claim 6. Regarding claims 8 and 16, Okuta et al disclose the screening of their libraries for active C23O enzymes, and disclose that their method results in enrichment for DNA sequences encoding C23O enzymes (see entire reference, particularly page 224). With respect to claims 9 and 17, it is an inherent property of the C23O enzymes taught by Okuta et al that they are oxidoreductases. Regarding claims 12-13, Okuta et al disclose that their soil and sea water samples comprise bacteria producing C23O enzymes (see, e.g., page 223, right column).

With regard to the rejection of claims 1-3, 5-6, 8-9, 12-17, and 20 as being anticipated by Okuta et al set forth in the prior Office action of June 15, 2007, the response traverses the rejection on the grounds that the Okuta et al reference does not teach the preparation of a "gene library" as required by the claims. The response argues that "As is well known in the art, a gene library represents the entire genome or expressed genes of an organism," while the library of Okuta et al "comprises only a specific type of genes obtained using degenerate primer pairs directed to the specific genes."

These arguments have been thoroughly considered but are not persuasive. First, applicants' own claims and specification make clear that the library of the

invention is not a standard gene library, but rather a library "enriched in DNA encoding a polypeptide with an activity of interest" (see preamble of claim 1; see also, e.g., the reference at page 6 of the specification to libraries "enriched in DNA encoding an enzyme activity of interest" and at page 8 of the specification to a gene library that "comprises an enzyme-encoding gene of interest"). The specification does not include any kind of limiting definition of the term "gene library" that would exclude the groups of nucleic acids prepared by Okuta et al, and, as indicated above, the steps used by Okuta et al to prepare their libraries meet the requirements of the claims, and result in the production of a library of nucleic acids enriched in genes encoding enzymes of interest. Further, not only do the amplified and cloned C23O genes disclosed by Okuta et al constitute a library, but the DNA prepared from cultivated bacteria and subsequently used as a target in amplification reactions by Okuta et al (see, e.g., page 222, last two lines of left column) is an enriched library of nucleic acids meeting the requirements of the claims. Accordingly, applicants' arguments are not persuasive.

Claim Rejections - 35 USC § 103

6. Claims 4, 7, 10-11, and 18-19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Okuta et al (Gene 212:221-228 [6/1998]) in view of Sarkar et al (Folia Microbiologica 38(1):29-32 [1993]).

Okuta et al disclose methods in which catechol 2,3-dioxygenase (C23O) gene libraries are prepared and in which DNA sequences in said libraries are identified (see entire reference, particular pages 222-224). The method of Okuta et al comprises a step of cultivating bacteria-containing samples of soil or sea water on media containing

substrates for C23O genes (specifically, phenol or crude oil), followed by PCR amplification and cloning of DNA templates prepared directly from bacterial cells growing "on phenol or crude oil as the carbon source" (see pages 222-224, particularly the right column of page 223). Okuta et al also disclose screening the libraries prepared by their methods for DNA sequences encoding their polypeptide of interest (i.e., encoding polypeptides having C23O sequences as determined by nucleic acid sequencing; see pages 222, right column and 224, right column). The phenol or crude oil containing media of Okuta et al is growth restricted in that only phenol-degrading bacteria grow on the media. Further, Okuta et al disclose the screening of their libraries for active C23O enzymes, and disclose that their method results in enrichment for DNA sequences encoding C23O enzymes (see entire reference, particularly page 224).

Okuta et al state that their method allows one to "isolate functional C23O genes without isolating bacteria," that the method is "useful for establishing a library of functional hybrid genes reflecting the diversity in the natural gene pool," and that their method is "generally applicable, and may be useful in establishing a divergent hybrid gene library for any gene family" (p. 225). Okuta et al further note that the "isolation and screening of novel enzymes are both important objectives in biotechnology," and that their method "may be useful for the exploitation of new genes useful for industry, medicine, and basic sciences" (p. 226). However, Okuta et al do not disclose the use of media containing a substrate meeting the requirements of claim 4, or disclose an "enzyme of interest" meeting the requirements of claims 10-11 and 18-19. Okuta et al also fail to disclose the particular growth restrictions of claim 11.

Sarkar et al teach that cellulases are produced "by many cellulolytic microorganisms," and disclose that *Bacillus thermoalcaliphilus* isolated from "the soil of a termite" produces a cellulase that is most stable at pH 8.5-9.5 and optimally active at 70°C (see entire reference, especially p. 29-30). Sarkar et al teach growth of this bacterium in media comprising cellulose at 60°C, pH 8.5 (p. 29). Sarkar et al further note that "the high temperature and high pH optima found here [with respect to the novel cellulose] give good promise for the practical application of the present enzyme and/or microorganism" (p. 32).

In view of the teachings of Sarkar et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Okuta et al so as to have prepared from a termite soil sample a library enriched for cellulase genes encoding thermostable cellulases such as that taught by Sarkar et al, and to have screening or selected such genes for further analysis. An ordinary artisan would have been motivated to have made such a modification for the advantage of, e.g., rapidly isolating and sequencing thermostable cellulase-encoding genes, and/or rapidly preparing recombinant forms of such cellulases for additional study or use. The usefulness of such cellulases is noted by Sarkar et al, and given the teachings of Okuta et al with regard to the general applicability of their method to other gene types, an ordinary artisan would have had a reasonable expectation that such methods could be carried out successfully. It is also noted that as it is a property of termite soil samples that such samples comprise microorganisms and are obtained from the environment, such samples meet the requirements of the instant claims.

With respect to claim 4, it is again noted that Sarkar et al disclose that cellulose is a substrate for cellulase, and teach growth of cellulase producing organisms in media comprising cellulose. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have selected cellulose as the substrate in practicing the method of Okuta et al in view of Sarkar et al for the advantage of enriching for the growth of the desired cellulase-producing bacteria. Regarding claim 7, it would also have been *prima facie* obvious to one of ordinary skill in the art to have selected the growth conditions taught by Sarkar et al for use in the method of Okuta et al in view of Sarkar et al in order to have assured optimal growth of thermostable-cellulase producing bacteria; the growth conditions taught by Sarkar et al meet the requirements of the claim. Regarding claims 11 and 19, it is noted that thermostable cellulases are among the enzymes encompassed by the claims. Finally, regarding claims 10 and 18, as Sarkar et al teach the usefulness of thermostable cellulases, and as Okuta et al teach that their method is generally applicable to any type of gene (see above), it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have also enriched and screened samples of the type taught by Sarkar et al for the presence of cellulase-related enzymes such as hemicellulases, using the method suggested by Okuta et al in view of Sarkar et al, and employing the well-known, relevant substrate for hemicellulase (specifically, hemicellulose), for the advantage of, e.g., rapidly isolating and identifying useful thermostable hemicellulases.

The response traverses the rejection on the grounds that Okuta et al does not teach preparation of a "gene library;" i.e., for the same reasons set forth in paragraph 6, above. Accordingly, the response to those arguments applies equally herein.

The combined references of Okuta et al and Sarkar et al suggest all the limitations of present claims 4, 7, 10-11, and 18-19, and therefore this rejection is maintained.

Terminal Disclaimer

7. The terminal disclaimer filed on December 17, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No. 6,723,504 has been reviewed and is accepted. The terminal disclaimer has been recorded.

8. In view of the acceptance of the above-noted terminal disclaimer, the prior rejection of claims 1-20 on the grounds of nonstatutory obviousness-type double patenting is withdrawn.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Diana B. Johannsen/
Primary Examiner, Art Unit 1634